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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/867,924	05/30/2001	Blake J. Roessler	UM-06191	7554

7590 07/15/2004
MEDLEN & CARROLL, LLP
Suite 2200
220 Montgomery Street
San Francisco, CA 94104

EXAMINER

FUBARA, BLESSING M.

ART UNIT PAPER NUMBER

1615

DATE MAILED: 07/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/867,924

Applicant(s)

ROESSLER ET AL.

Examiner

Blessing M. Fubara

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 06/03/02
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Examiner acknowledges receipt of IDS filed 06/03/02, change of power of attorney filed 09/17/02, letter of status inquiry filed 12/02/02, and letter requesting to know status of application filed 06/16/04.

Priority

1. Applicants' claim for domestic priority under 35 U.S.C. 119(e), for provisional application number 60/208,728 is acknowledged.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

2. Claims 1-15, 25-29, 32-45 and 60-64 are rejected under 35 U.S.C. 102(a) as being anticipated by Bielinska et al. ("Applications of membrane-based dendrimer/DNA complexes for solid phase transfection in vitro and in vivo," Biomaterials, 21 (2000) 877-887, published May 2000 and cited by applicants on Form PTO-1449).

Bielinska discloses membrane based dendrimer/DNA complexes for solid phase transfection in vitro and in vivo (Title and abstract). PLGA polymer membrane, phosphatidylglycerol (PG)-collagen/fibronectin membranes are utilized for topical delivery of the DNA/dendrimer complexes into skin cells and cultured cells were successfully transfected with the DNA/collagen complex (877-885). Bielinska meets the limitations of the claims.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 16-24, 30, 31 and 46-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bielinska et al. ("Applications of membrane-based dendrimer/DNA complexes for solid phase transfection in vitro and in vivo," *Biomaterials*, 21 (2000) 877-887, published May 2000 and cited by applicants on Form PTO-1449) and Shea et al. (WO 99/58656).

Bielinska discloses DNA/dendrimer system that is topically used to deliver nucleic acid. Bielinska does not disclose applying the complex to a target site to treat wound.

Shea discloses a composition comprising nucleic acid segment that is associated with a structural matrix (claim 1). The structural matrix is biodegradable and biocompatible matrix comprised of lactic acid/glycolic acid copolymer (claims 6-12) or polysaccharide (claims 13-150) and the nucleic acid is DNA (claim 17). The DNA or nucleic acid segment encodes growth factors, hormones proteins (page 15, lines 28-31 and page 16, lines 14-17); and the composition is used to promote wound healing (page 19, lines 14-18) by placing the composition, which is the matrix-gene composition, in contact with the target site or tissue (page 55, line 6 and claims 19-25). Since Shea applies a DNA/porous matrix of PLGA to a wound site to promote wound healing and since Bielinska topically applies DNA/dendrimer complex of PLGA for delivery of DNA/gene to a target site, it would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the DNA/dendrimer of Bielinska to a wound site. One

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having ordinary skill in the art would have been motivated to apply the DNA/dendrimer of Bielinska at a target site as disclosed by Shea with the expectation that the DNA/dendrimer complex will promote wound healing.


5. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

 Blessing Fubara
Patent Examiner
Tech. Center 1600


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TEC. CENTER 1600

FORM PTO-1449
(Modified)U.S. Department of Commerce
Patent and Trademark Office

Attorney Docket No.: UM-06191

Serial No.: 09/867,927

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Use Several Sheets If Necessary)

(37 CFR § 1.98(b))

Applicant: Blake J. Roessler *et al.*

Filing Date: 05/30/01

Group Art Unit:

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Serial / Patent Number	Issue Date	Applicant / Patentee	Class	Subclass	Filing Date
BF	1	4,507,466	03-26-85	Tomalia <i>et al.</i>	528	332	01-07-83
	2	4,558,120	12-10-85	Tomalia <i>et al.</i>	528	363	12-27-83
	3	4,568,737	02-04-86	Tomalia <i>et al.</i>	528	332	08-17-84
	4	4,587,329	05-06-86	Tomalia <i>et al.</i>	528	363	07-19-85
	5	4,631,337	12-23-86	Tomalia <i>et al.</i>	528	391	07-15-85
	6	4,694,064	09-15-87	Tomalia <i>et al.</i>	528	332	02-28-86
	7	4,713,975	12-22-87	Tomalia <i>et al.</i>	73	865.8	05-30-86
	8	4,737,550	04-12-88	Tomalia	524	418	12-08-86
	9	4,857,599	08-15-89	Tomalia <i>et al.</i>	525	259	02-08-88
	10	4,871,779	10-03-89	Killat <i>et al.</i>	521	28	12-23-85
	11	5,338,532	08-16-94	Tomalia <i>et al.</i>	424	1.49	02-13-91
	12	5,387,617	02-07-95	Hedstrand <i>et al.</i>	521	79	11-08-93
	13	5,393,797	02-28-95	Hedstrand <i>et al.</i>	521	134	06-13-94
	14	5,393,795	02-28-95	Hedstrand <i>et al.</i>	521	134	06-13-94
	15	5,527,524	06-18-96	Tomalia <i>et al.</i>	424	1.33	04-05-93
	16	5,560,929	10-01-96	Hedstrand <i>et al.</i>	424	486	11-12-93
	17	5,773,527	06-30-98	Tomalia <i>et al.</i>	525	417	01-20-95
	18	5,631,329	05-20-97	Yin <i>et al.</i>	525	417	03-21-95
	19	5,902,863	05-11-99	Dvornic <i>et al.</i>	525	431	07-21-97
	20	5,795,582	08-18-98	Wright	424	400	02-07-96
	21	5,898,005	04-27-99	Singh <i>et al.</i>	436	527	04-13-94
	22	5,861,319	01-19-99	Lin <i>et al.</i>	436	527	10-28-94
	23	5,661,025	08-26-97	Szoka, Jr. <i>et al.</i>	435	458	06-07-95
	24	4,965,128	10-23-90	Greidanus <i>et al.</i>	428	398	02-26-88
BF	25	4,161,948	07-24-79	Bichon	602	58	01-16-78

FOREIGN PATENTS OR PUBLISHED FOREIGN PATENT APPLICATIONS

		Document Number	Publication Date	Country / Patent Office	Class	Subclass	Translation	
							Yes	No
BF	26	EP0099758	10-1988	EP				
BF	27	WO 99/58656	11-1999	NO				
BF	28	WO 95/24221	09-1995	NO				

OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)

BF	29	Winter, Nature 193:293 [1962]
BF	30	Kannon and Garrett, Dermatol. Surg. 21:583 [1995]

Examiner: Blessing Fubara

Date Considered: 6-25-04

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449
(Modified)U.S. Department of Commerce
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Attorney Docket No.: UM-06191

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Use Several Sheets If Necessary)Applicant: Blake J. Roessler *et al.*

Filing Date: 05/30/01

Group Art Unit:

(37 CFR § 1.98(b))

OTHER DOCUMENTS (Including Articles, Title, Date, Relevant Pages, Place of Publication)

- | | |
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| 31 | Davies, Burns 10:94 [1983] |
| 32 | Riley, Am. Fam. Physician 24:107 [1981] |
| 33 | Ye <i>et al.</i> , Mol Med Today 4:431 [1998] |
| 34 | Gerwitz <i>et al.</i> , Blood 92:712 [1998] |
| 35 | Tomalia <i>et al.</i> , Agnew Chem Int Ed Engl 29:138 [1990] |
| 36 | Frechet, Science 263:1710 [1994] |
| 37 | Kukowska-Latallo <i>et al.</i> , Proc Natl Acad Sci USA 93:4897 [1996] |
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| 41 | Trainer <i>et al.</i> , Human Mol Gen 6:1761 [1997] |
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| 46 | Tomalia, Advanced Materials 6:529 [1994] |
| 47 | Yin <i>et al.</i> , J. Am. Chem. Soc., 120:2678 [1998] |
| 48 | Bourne <i>et al.</i> , J. Magn. Reson. Imag., 6:305 [1996] |
| 49 | Singh <i>et al.</i> , Clin. Chem., 40:1845 [1994] |
| 50 | Wu <i>et al.</i> , Bioorg. Med. Chem. Lett., 4:449 [1994] |
| 51 | Wiener <i>et al.</i> , Magn. Reson. Med. 31:1 [1994] |
| 52 | Barth <i>et al.</i> , Bioconjugate Chem. 5:58 [1994] |
| 53 | Duncan and Malik, Control Rel. Bioact. Mater. 23:105 [1996] |
| 54 | Baker <i>et al.</i> , Anal. Chem. 69:990 [1997] |
| 55 | Urdea and Hom, Science 261:534 [1993] |
| 56 | Pavlova <i>et al.</i> , Biomaterials 14(13):1024 [1993] |
| 57 | Sottosanti, Compendium 13(3):226-8, 230, 232-4 [1992] |
| 58 | Brandl <i>et al.</i> , Adv Biochem Eng Biotechnol ;41:77 [1990] |
| 59 | Braunegg <i>et al.</i> , J Biotechnol 65(2-3):127 [1998] |
| 60 | Gac <i>et al.</i> , J Drug Target 7(5):393 [2000] |

Examiner:

Blessing Furber

Date Considered:

6-25-04

EXAMINER:

Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[illegible]

Notice of References Cited	Application/Control No. 09/867,924	Applicant(s)/Patent Under Reexamination ROESSLER ET AL.	
	Examiner Blessing M. Fubara	Art Unit 1615	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-			
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

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*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
*	N	WO 99/58656	11-1999	WO	SHEA	-
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
*	U	BIELINSKA et al. ("Applications of membrane-based dendrimer/DNA complexes for solid phase transfection in vitro and in vivo," Biomaterials, 21 (2000) 877-887, published May 2000).
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

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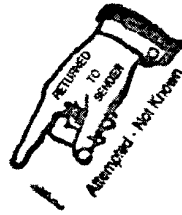
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